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| 10/814,480 | 03/29/2004 | Nicholas M. Valiante JR. | 20426.003 | 9427 |

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Chiron Corporation
Intellectual Property - R440
P.O. Box 8097
Emeryville, CA 94662-8097

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| EXAMINER |
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CHONG, YONG SOO

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| ART UNIT | PAPER NUMBER |
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1617

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on 5/8/2006. Claim(s) 1-20, 22-23, 25, 27-29, 31-35 has/have been cancelled. Claim(s) 21, 24, 26, 30, 36-39 is/are pending. Claim(s) 21 has/have been amended. Claim(s) 21, 24, 26, 30, 36-39 is/are examined herein. Applicant's arguments have been fully considered but found persuasive to withdraw all rejections on record. The following new rejection will now apply.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham vs John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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Claim(s) 21, 24, 26, 36-39 is/are rejected under 35 U.S.C. 103(a) as being obvious over Das et al. (US Patent 6,596,746 B1) in view of Klaviniskis et al. (US Application 2003/014792 A1).

The instant claims are directed to a composition comprising a SMIP compound of formula XXI and an antigen.

Das et al. teach novel cyclic compounds and their use in the treatment of immunologic and oncologic disorders (abstract). A preferred compound is N-(2-chloro-6-methylphenyl)-2-{{2-(4-morpholinylmethyl)-1H-benzimidazole-5-yl}amino]-5-thiazolecarboxamide (col. 297, lines 18-20). Some examples of disorders that can be treated include respiratory allergies, such as asthma (col. 24, line 1), and colon (col. 23, line 64), breast, and lung cancer (col. 24, lines 62-64). Das et al. also teach that other therapeutic agents may be administered with the compounds of the instant invention (col. 23, lines 34-37), such as other anti-cancer agents, biological response modifiers, immune modulators, and monoclonal antibodies (col. 27, lines 63-66).

However, Das et al. fail to disclose specifically an antigen in the composition.

Klaviniskis et al. disclose a composition comprising spores of *Bacillus subtilis* as a method of stimulating immune responsiveness in a subject. The spores have an adjuvant, immunomodulatory, immune potentiation effect in a subject (abstract). Klaviniskis et al. also disclose that antigens can be used as adjuvant in the present composition (pg. 15, section 0155) to boost an immune response in a mammal (abstract). In addition to the MF59 adjuvant (pg. 2, section 0014), other antigens that are mentioned to be useful are influenza, hemagglutinin, and neuraminidase (pg. 14,

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section 0147). Furthermore, Klaviniskis et al. disclose that the present composition can be used to treat allergic asthma and lung, breast, and colon cancers (pg. 7, section 0082-0083).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to combine the adjuvants as taught by Klaviniskis et al. with the composition as taught by Das et al.

A person of ordinary skill in the art would have been motivated to make this combination because (1) both Das and Klaviniskis et al. disclose a method of treating immunologic disorders, such as asthma, as well as breast, lung, and colon cancers; (2) Das et al. teaches the use of other therapeutic agents in the composition, such as other anti-cancer agents, biological response modifiers, immune modulators, and monoclonal antibodies; (3) Klaviniskis et al. disclose a composition comprising spores, which contain adjuvants that have an immunomodulatory effect and stimulates immune responsiveness. Therefore, one of ordinary skill in the art would have had a reasonable expectancy to successfully make a composition that would effectively treat immunologic disorders, such as asthma, as well as breast, lung, and colon cancers by stimulating the immune system and enhancing an immune response.

Examiner respectfully points out that the intended use of claim 26, directed to the biological function of the composition is given no patentable weight.

It is well known in Patent Law that if applicants are claiming a biological pathway as the basis for their invention then a mechanism by which the active ingredient gives the pharmacological effect does not alter the fact that the compound has been

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previously used to obtain the same pharmacological effects which would result from the claimed method. The patient, condition to be treated, and the effect are the same. An explanation of why that effect occurs does not make novel or even unobvious the treatment of the conditions encompasses by the claims.

Claim Objections

Claim 30 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC

SHENG JIN WANG
PRIMARY EXAMINER